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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,977	06/22/2006	Stefan Johan Koppelman	677132000200	8397

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MORRISON & FOERSTER LLP
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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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08/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,977	Applicant(s) KOPPELMAN ET AL.	
	Examiner NORA M. ROONEY	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 05/28/2010 is acknowledged.
2. Newly added claims 17-22 are pending.
3. Newly submitted claims 17-20 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth in the Restriction Requirement mailed on 05/26/2009. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
4. Claims 21-22 are currently under consideration as they read on a method to desensitize a subject to an allergic reaction to 2S albumin comprising administering reduced and alkylated 2S albumin to the subject.
5. The following new ground of rejection is necessitated by Applicant's amendment filed on 05/28/2010.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/074250 (IDS filed on 08/22/2006) in view of Bartolome et al. (PTO-892; Reference U).

WO 02/074250 teaches a method for treating an individual suffering from food allergy comprising administering to said individual a therapeutically effective amount of an allergen modified by reduction and alkylation wherein the allergen is brazil nut 2S albumin (In particular, page 3, line 24 to page 4, line 30, page 40, lines 1-29, Appendix 8, page 176, claims, whole document); wherein said reduction uses a reducing agent selected from the group consisting of 2-mercaptoethanol, dithiothreitol, dithioerythritol, and tributylphosphine (In particular, page 32, line 5-21); said alkylation uses an alkylating agent chosen selected from the group consisting of N-ethylmalimide, cystamine, iodoacetamide, and iodoacetic acid (In particular, page 32, lines 5-21); wherein administration induces production of Thelper-1 mediated subclasses of IgG antibodies (In particular, page 3, line 24 to page 4, line 30, page 40, lines 1-29, whole document); and results in down regulating the production of IgE antibodies (In particular, page 3, line 24 to page 4, line 30, page 40, lines 1-29, whole document).

Bartolome et al. teaches that 2S albumin Ber e 1 major allergen of Brazil nut is a sulfur-rich allergen having 8% cysteine that forms disulfide bonds which are important for its conserved 2 S albumin structure. (In particular, page 136 right column) Ber e 1 is resistant to proteolytic digestion due to the disulfide bonds and the reference teaches that the stable structure allows the protein to reach and pass through the mucosal membrane of the intestine without

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complete enzymatic proteolytic degradation or acidic denaturation in the digestive tract, conferring its allergenic properties (In particular, last paragraph).

It would have been obvious to combine the specific teachings within the WO 02/074250 reference to arrive at the instantly claimed invention, particularly because Bartolome et al. teaches that the stable conformational structure of the Ber e 1 protein contributes to its allergenicity. It would have been obvious to alter the conformational structure of the Ber e 1 major allergen of Brazil nuts before administering the allergen to treat allergies to brazil nuts. WO 02/074250 specifically teaches how to alter the conformational structure of a protein due to disulfide bonds by reduction and alkylation to result in allergens, such as Ber e 1, with reduced IgE binding.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 05/28/2010 have been fully considered, but are not found persuasive.

Applicant argues:

"...although Panacea is clearly aware that reduction and alkylation are methods to diminish allergenicity, for this particular protein, only production of mutants is described. (See page 100-126 of Panacea.) In particular, starting on page 113, the IgE binding epitopes are mapped and the critical amino acids are set forth in Table 25 on page 117; T cell epitopes are also mapped. Table 26 sets forth the list of mutants and does not even include cysteine-depleted mutants. Thus, the reader of the enclosed document

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would conclude that the authors found it necessary to go through the complicated process of preparing mutants rather than undertaking the relatively simple processes of reduction and alkylation. In effect, Panacea teaches away from the invention as now claimed."

It is the Examiner's position that WO 02/074250 specifically teaches that allergens may be reduced and alkylated in order to disrupt one or more disulfide bonds that are present in the natural allergen and that Bartolome et al. teaches that 2S albumin Ber e 1 major allergens of Brazil nut is a sulfur-rich allergen having 8% cysteine that form disulfide bonds which are important for its conserved 2 S albumin structure. It would be obvious to disrupt the disulfide bonds of the Ber e 1 protein from a combination of the teachings of the references and to administer the resulting allergen to treat brazil nut allergy.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A

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message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 16, 2010

/Nora M Rooney/

Primary Examiner, Art Unit 1644